Hazards, Hazards Everywhere!

Partnering Pharmacy and Occupational Health for Success with Hazardous Drug Management

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Disclosures

• The presenters have no disclosures
Learning Objectives

- Describe how an assessment or risk can be developed to support efforts of occupational health professions.
- Describe the components of a practical medical surveillance program for hazardous drugs.
- Identify approaches to ensure health care workers are notified of their risk of exposure with hazardous medications.
What Keeps Me Up At Night?

• Sue Crump

• Mixed chemotherapy as a pharmacist for 23 years

• Died of pancreatic cancer at age 55
Exposure in HealthCare

- 8 million workers exposed to hazardous drugs or hazardous drug waste
  - Nursing
  - Pharmacy
  - Providers
  - Environmental service workers
- Studies have demonstrated impact of exposure
  - Acute and chronic health effects
    - GI: pain, nausea, vomiting, diarrhea
    - Derm: Rashes, flushing, hair thinning/loss, irritation of skin, eyes, and mucous membranes.
    - Reproductive risks: (infertility, spontaneous abortion, congenital malformations
      - Leukemia and cancers
  - Chemotherapy has been found in the urine of health care workers
Best Practice History

- 1983: American Society of Health System Pharmacists (ASHP) publishes practice spotlight and recommendations for safe handling of hazardous drugs in hospital setting
  - Introduced the concept of hazardous drug as “therapeutic drugs with adverse effects that could endanger healthcare workers”
- 1985 and 1990: ASHP publishes technical assistance bulletin
- 1995: OSHA uses ASHP criteria to evaluate drugs
- 2004: NIOSH first “alert” establishing general policy for identification of hazardous drugs
- 2007: USP 797 chapter includes hazardous drugs
• Three categories:
  – Table I: Antineoplastic - cisplatin
  – Table II: Non-antineoplastic - phenytoin, estrogens
  – Table III: Reproductive hazards - oxytocin, finasteride

• Assessment of Risk
  – Allows for organizations to define how hazardous meds will be handled (excludes NIOSH table I)
What is USP?

- United States Pharmacopia Convention (USP)
- Non-government, not for profit organization
- NO REGULATORY AUTHORITY!
- Defines standards for quality and purity that impact healthcare and other industries
  - Drug purity
  - Standards for compounding
  - Standards for employee protection from exposure to hazardous medications
- Publish recommendations
  - Practice
  - Incidents
- Enforcement comes from other agencies adopting standards for enforcement
  - Joint Commission helped by mandating pharmacy prep of non-urgent admixtures
  - CMS interpretive guidance October 30, 2015

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## USP 800 Highlights

<table>
<thead>
<tr>
<th>USP 800</th>
<th></th>
</tr>
</thead>
</table>
| **Focus** | • Employee safety  
            • Hazardous drug management including receiving, storage, compounding, dispensing, administration, and disposal |
| **Effective Date** | December 1, 2019  
*revised from original date of July 1, 2018 |
| **Impact** | • All healthcare workers that handle hazardous drugs  
            • All practice settings  
            • Home care  
            • Retail pharmacy  
            • Physician offices |
| **Primary engineering control (hood)** | Class II Biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI) |
| **Secondary engineering control** | Closed-system transfer devices |
| **Personal Protective Equipment** | Gowns, gloves, goggles, face-shields, N-95, PAPR/CAPR |
| **Enforcement** | OSHA, *to be determined* |
Components of USP 800

- Facilities
- Assessment of Risk
- Personnel acknowledgement and medical surveillance
- Education and training
- Personal Protective Equipment
- Use of closed-system transfer devices (CSTDs)
- Environmental monitoring
- Others!
Our Approach
BJC HealthCare

1. Alton Memorial Hospital
2. Barnes-Jewish Hospital
3. Barnes-Jewish St. Peters Hospital
4. Barnes-Jewish West County Hospital
5. Boone Hospital Center
6. Christian Hospital
7. Memorial Hospital Belleville
8. Memorial Hospital East
9. Missouri Baptist Medical Center
10. Missouri Baptist Sullivan Hospital
11. Parkland Health Center
12. Parkland Health Center Bonne Terre
13. Progress West Hospital
14. St. Louis Children’s Hospital
15. The Rehabilitation Institute of St. Louis
Beginning the USP 800 Journey

- BJC USP 800 team formed spring 2016
- Gaps identified
  - Facilities (34 compounding locations)
    - Varied design, layout, and processes
  - Compliance to policy
  - Variation in training/expectations
    - PPE
    - Closed system transfer devices
  - Medical surveillance
  - Variation in what makes a drug hazardous (15 hospitals, 15 different lists of hazardous drugs!)
- Competing priorities (or opportunities?)
  - New EMR deployment
  - New leadership and strategic direction
Questions We Asked

• Why is this happening to us/WIIFM?
• What PPE is required for nursing staff?
• Can we use the new EMR to help address the PPE requirement?
• What can nurses manipulate on the floor vs. what has to be done in pharmacy?
• Can we develop a standardized hazardous drug list for all entities?
• How will we operationalize a common approach?
Step 1: NIOSH Table 5 Review

- Provides general guidance for drug, formulation, activity, and recommended controls and PPE

- Our internal review of table 5 identified several concerns:
  - Amount of PPE required
  - Additional cost (PPE, CSTDs)
  - Compliance with expectations/policy for PPE
  - Fit testing demands on OH
Step 2: Evaluate Options

• Two options with USP 800:
  – Treat all hazardous drugs with all required containment strategies in USP 800
  – Perform an assessment of risk that includes the following:
    • Drug
    • Dose form
    • Risk of exposure
    • Packaging
    • Manipulation
    • Documentation of alternative containment strategies and/or work practices
    • Review annually and document
Step 3: Determine Approach

• BJC selected to perform an Assessment of Risk (AoR) for the system to support development of a system policy
  – Allowed for consistency in approach
• Identified team members included pharmacy, safety, design and construction, nursing and a trained facilitator
• Weekly meetings for ~6 months
• Typical agenda topics:
  – Reviewed drugs and dose form available in BJC
  – Identify who should perform specific activities (nursing vs. pharmacy)
    • Splitting
    • Crushing
    • Emergent compounding
  – Identify if there are alternative delivery methods (premixed products, oral liquids)
  – Identified necessary PPE for each risk level and activity
Step 4: Get to Work!

- Team decided to categorize based on risk definitions (high risk, moderate risk, reproductive risk) and not the NIOSH table (I, II, III)
- Completed table to identify PPE for each risk category and dose form
- Agreed upon standardized template for the AoR
  - Categorized into high, moderate, and reproductive risk
    - Pharmacy reviewed all medications from a risk to the employee vs. NIOSH current listing/category and newly added drugs to formulary to determine which category each medication should be classified within
    - Dosage form (oral liquid, subQ injection, irrigation, etc.) and potential for manipulation outside of pharmacy were considered as medications were categorized
    - Step by step workflow (receiving, storage, manipulation, dispensing, administration, disposal) design
    - PPE was defined for each of these templates (supported by EH&S)
- Supported development of interim hazardous drug policy
- Team recommendation to phase roll out for AoR
  - Phase I- Sept 1, 2018, “high” risk list only
  - Phase II- all hazardous drugs (NIOSH and others based on criteria)
PPE for High Risk Drugs - Based on Dose Form and Activity

Personal Protective Equipment (PPE) and Engineering Controls for Handling HIGH Risk Hazardous Drugs (HDs)

BJC Healthcare rev: 7/2018

Chemotherapy gloves must meet ASTM D6978 standards. Gloves must be changed every 30 minutes and/or when torn, punctured, or contaminated and as directed by patient care practice/policy. Employees may use full PPE for ALL handling of HIGH risk HDs if desired. (N95/PAPR/CAIR require medical evaluation, N95 requires fit testing.) Departmental Policy and Procedure for handling of HDs should be followed if it has been developed to address handling of a specific HD in a unique situation.

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Activity</th>
<th>Gloves</th>
<th>Gown</th>
<th>Head/Hair cover includes board &amp; mustache cover, booties</th>
<th>Eye/Face Protection</th>
<th>Respiratory Protection: N95/PAPR/CAIR when indicated; N95/PAPR/CAIR protects from particulates but NOT from gases or vapors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any formulation</td>
<td>Receiving, unpacking and placing in storage</td>
<td>Receiving/unpacking – Double, otherwise, Single Chemotherapy (and PPE based on storage room requirements)</td>
<td>No unless spills and leaks occur</td>
<td>No</td>
<td>No</td>
<td>No unless spills and leaks occur, then N95/PAPR/CAIR</td>
</tr>
<tr>
<td>Intact tablet or capsule</td>
<td>Administration, labelling of repackaged product</td>
<td>Single Chemotherapy</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Counting and packaging</td>
<td>Single Chemotherapy</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Manipulated tablets or capsules</td>
<td>Cutting, crushing or otherwise manipulating (MUST BE DONE IN PHARMACY)</td>
<td>Double Chemotherapy</td>
<td>Impervious Chemo Gown</td>
<td>No (unless BSC located in sterile room)</td>
<td>No if done in BSC/CACI. If no BSC/CACI, goggles, designated area and spill pad required.</td>
<td>No if done in BSC/CACI. If no BSC/CACI, goggles, designated area and spill pad required.</td>
</tr>
<tr>
<td></td>
<td>Counting, packaging, and labelling</td>
<td>Double Chemotherapy</td>
<td>Impervious Chemo Gown</td>
<td>No must be done in BSC/CACI. If no BSC/CACI, goggles, designated area and spill pad required.</td>
<td>No if done in BSC/CACI. If no BSC/CACI, goggles, designated area and spill pad required.</td>
<td>No if done in BSC/CACI. If no BSC/CACI, goggles, designated area and spill pad required.</td>
</tr>
<tr>
<td></td>
<td>Administration</td>
<td>Double Chemotherapy</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No unless risk for vomit or spill up</td>
</tr>
<tr>
<td>Oral liquid drug</td>
<td>Labeling only2</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Repackaging - drawing into oral syringe, transfer from stock container to dispensing container</td>
<td>Single Chemotherapy</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No unless risk of splash</td>
</tr>
<tr>
<td></td>
<td>Compounding - combining HD with diluent or vehicle (including powder to liquid)</td>
<td>Double Chemotherapy</td>
<td>Impervious Chemo Gown</td>
<td>Yes</td>
<td>No if done in BSC/CACI. If no BSC/CACI, goggles, designated area and spill pad required.</td>
<td>No if done in BSC/CACI. If no BSC/CACI, goggles, designated area and spill pad required.</td>
</tr>
<tr>
<td></td>
<td>Administration, labeling repackaged drug</td>
<td>Single Chemotherapy</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No unless risk for vomit or spill up</td>
</tr>
</tbody>
</table>

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Definitions: High Risk

• High Risk Hazardous Drug - meets at least one of the following criteria:
  – Drugs categorized as NIOSH Table 1 medications.
  – Drugs that are carcinogenic, teratogenic, or cause reproductive toxicity, developmental toxicity, organ toxicity or genotoxicity in humans and/or animals at doses below or equal to maximum recommended dose equivalent and evidence of harm in humans (pregnancy category D or X). This could include drugs that have Manufacturer Safe Handling Guidance (MSHG) or information in the medication’s package insert about handling the drug safely and includes medications reviewed and still pending NIOSH review.
  – Drugs that have structure and toxicity profiles that mimic existing drugs determined to be high risk hazardous drugs prior to NIOSH review.
High List Items (in addition to all NIOSH table I)

NIOSH Drugs – Consideration for Elevating from Table 2 or 3 to High Risk

<table>
<thead>
<tr>
<th>Drug</th>
<th>IARC 1 Carcinogen</th>
<th>NTP Carcinogen</th>
<th>Pregnancy Category</th>
<th>Toxicity at Low Dose</th>
<th>MSHG</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bevacizumab</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Added to NIOSH 2018 as high</td>
</tr>
<tr>
<td>Blinatumumab</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Added to NIOSH 2018 as high</td>
</tr>
<tr>
<td>Ceritinib</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Added to 2018</td>
</tr>
<tr>
<td>Cidofovir</td>
<td>No</td>
<td>No</td>
<td>C</td>
<td>No</td>
<td>Yes</td>
<td>High Risk</td>
</tr>
<tr>
<td>Dexrazoxane</td>
<td>No</td>
<td>No</td>
<td>C</td>
<td>Yes</td>
<td>Yes</td>
<td>High Risk</td>
</tr>
<tr>
<td>Ganciclovir</td>
<td>No</td>
<td>No</td>
<td>C</td>
<td>No</td>
<td>Yes</td>
<td>High Risk</td>
</tr>
<tr>
<td>Leflunomide</td>
<td>No</td>
<td>No</td>
<td>X</td>
<td>Yes</td>
<td>Yes</td>
<td>High Risk</td>
</tr>
<tr>
<td>Lenalidomide</td>
<td>No</td>
<td>No</td>
<td>X</td>
<td>Yes</td>
<td>Yes</td>
<td>High Risk</td>
</tr>
<tr>
<td>Lenvatinib</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Added to 2018</td>
</tr>
<tr>
<td>Mycophenolate</td>
<td>No</td>
<td>No</td>
<td>D</td>
<td>Yes</td>
<td></td>
<td>High Risk</td>
</tr>
<tr>
<td>Raloxifene</td>
<td>No</td>
<td>No</td>
<td>X</td>
<td>Yes</td>
<td></td>
<td>High Risk</td>
</tr>
<tr>
<td>Teriflunomide</td>
<td>No</td>
<td>No</td>
<td>X</td>
<td>Yes</td>
<td></td>
<td>High Risk+++</td>
</tr>
<tr>
<td>Thalidomide</td>
<td>No</td>
<td>No</td>
<td>X</td>
<td>No</td>
<td>Yes</td>
<td>High Risk</td>
</tr>
</tbody>
</table>

Table 1 new drugs from NIOSH 2018 *not yet finalized but anticipated to remain NIOSH table I

<table>
<thead>
<tr>
<th>Drug</th>
<th>IARC 1 Carcinogen</th>
<th>NTP Carcinogen</th>
<th>Pregnancy Category</th>
<th>Toxicity at Low Dose</th>
<th>MSHG</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trabectedin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Added to 2018 table I- add to HIGH</td>
</tr>
<tr>
<td>Trastuzumab</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Added to 2018 table I- move to HIGH</td>
</tr>
</tbody>
</table>

Added to High Risk Table after evaluated by New Criteria

<table>
<thead>
<tr>
<th>Drug</th>
<th>IARC 1 Carcinogen</th>
<th>NTP Carcinogen</th>
<th>Pregnancy Category</th>
<th>Toxicity at Low Dose</th>
<th>MSHG</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azathioprine</td>
<td>Yes</td>
<td>Yes</td>
<td>D</td>
<td>No</td>
<td>Yes</td>
<td>- Move to HIGH</td>
</tr>
</tbody>
</table>

Table 3

<table>
<thead>
<tr>
<th>Drug</th>
<th>IARC 1 Carcinogen</th>
<th>NTP Carcinogen</th>
<th>Pregnancy Category</th>
<th>Toxicity at Low Dose</th>
<th>MSHG</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dronedarone</td>
<td>No</td>
<td>No</td>
<td>X</td>
<td>Yes</td>
<td></td>
<td>High Risk</td>
</tr>
<tr>
<td>Pamidronate</td>
<td>No</td>
<td>No</td>
<td>D</td>
<td>Yes</td>
<td></td>
<td>High Risk</td>
</tr>
<tr>
<td>Ribavirin</td>
<td>No</td>
<td>No</td>
<td>X</td>
<td>Yes</td>
<td>No</td>
<td>High Risk</td>
</tr>
<tr>
<td>Zoledronic Acid</td>
<td>No</td>
<td>No</td>
<td>D</td>
<td>Yes</td>
<td></td>
<td>High Risk</td>
</tr>
</tbody>
</table>

Other

<table>
<thead>
<tr>
<th>Drug</th>
<th>IARC 1 Carcinogen</th>
<th>NTP Carcinogen</th>
<th>Pregnancy Category</th>
<th>Toxicity at Low Dose</th>
<th>MSHG</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gefitinib</td>
<td>No</td>
<td>No</td>
<td>D</td>
<td>in rats but not rabbits</td>
<td></td>
<td>High Risk*- not on any list currently but add to high</td>
</tr>
<tr>
<td>Lapatinib</td>
<td>No</td>
<td>No</td>
<td>D</td>
<td>Embryofetal effects at low dose in rabbits but not rats</td>
<td></td>
<td>High Risk**- not on any list but move to high</td>
</tr>
</tbody>
</table>
## AoR Templates

**BJC HealthCare**

### Hazardous Drug Assessment of Risk

**Hospital/Service Organization:**

<table>
<thead>
<tr>
<th>Drug: Zoledronic Acid</th>
<th>Dosage Form: Intravenous Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of HD: Reproductive risk only (NIOSH 3)</td>
<td>IARC Classification: No</td>
</tr>
<tr>
<td>Level of risk: High</td>
<td>AHFS Classification: 92-24 bone resorption inhibitor</td>
</tr>
<tr>
<td>Reason for Exemption: Pregnancy category D</td>
<td>MSHG: No</td>
</tr>
</tbody>
</table>

**NOTE:** This is a summary of requirements. Full requirements are listed in USP Chapters <795>, <797>, <800>, the NIOSH Alert and List of Hazardous Drugs, and health-system policy and procedures.

<table>
<thead>
<tr>
<th>Activity</th>
<th>USP Chapter &lt;800&gt; and NIOSH Considerations</th>
<th>Organizational Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchasing</td>
<td></td>
<td>Follow &lt;800&gt;</td>
</tr>
<tr>
<td>Receipt</td>
<td>Unpack in neutral/nominal-pressure area. Spill kit and respirator available</td>
<td></td>
</tr>
<tr>
<td>Required PPE - Receipt</td>
<td>Minimum PPE required for activity</td>
<td></td>
</tr>
<tr>
<td>Transport from receipt to storage</td>
<td>In container that minimizes risk of breakage or leakage</td>
<td></td>
</tr>
<tr>
<td>Storage</td>
<td>Separate from non-HD. Separate room which is negative pressure, externally vented, and has at least 12 air changes per hour (ACPH)</td>
<td></td>
</tr>
<tr>
<td>Transport from storage to compounding area</td>
<td>In container that minimizes risk of breakage or leakage</td>
<td></td>
</tr>
<tr>
<td>Transport from storage to dispensing area</td>
<td>In container that minimizes risk of breakage or leakage</td>
<td></td>
</tr>
<tr>
<td>Non-sterile compounding area(s)</td>
<td>Meets USP Chapters &lt;795&gt; and &lt;800&gt; requirements</td>
<td></td>
</tr>
<tr>
<td>Required PPE - Compounding/Preparation</td>
<td>Minimum PPE required for activity</td>
<td></td>
</tr>
<tr>
<td>Sterile compounding area(s)</td>
<td>Meets USP Chapters &lt;797&gt; and &lt;800&gt; requirements</td>
<td></td>
</tr>
<tr>
<td>Primary Engineering Control</td>
<td>Dependent on sterile vs non-sterile compounding</td>
<td></td>
</tr>
<tr>
<td>Supplemental Engineering Control</td>
<td>CSTO considered for compounding</td>
<td></td>
</tr>
</tbody>
</table>

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Step 5: Implement and Assess

Benefits/Monitor

• Training and education is ongoing; final implementation will occur no later than Dec 1, 2019!

• Initial benefits identified to our approach:
  – Reduced PPE burden
  – Standardized approach
  – Determination for those requiring fit testing
  – Communication about the “risks” of hazardous drug handling

• Monitoring:
  – Integrated into daily huddles
  – Environmental rounds
  – Occupational exposure reports
The Spill... Success!
USP 800: The Impact on Occupational Health
Key Factors That Impact OH

• Personal protective equipment:
  – Respiratory protection: N95s, PAPRs/CAPRs
  – Gowns
  – Gloves

• Medical Surveillance Program
• HD exposure follow-up
• Acknowledgement of risk
• Requests for alternative assignments
Medical Surveillance General Principles

• Recommendation under USP 800

• Considered a second line of defense

• Purpose:
  – Minimize adverse health risks through identification of trends
  – Monitor effectiveness of primary exposure prevention
    • Engineering controls
    • Administrative controls
    • Work practice controls
    • PPE
    • Education program
Medical Surveillance General Principles

• Recommendations available, no regulatory requirements
  – Oncology Nursing Society (ONS)
  – National Institute for Occupational Safety and Health (NIOSH)
  – Occupational Safety and Health Administration (OSHA)

• Key elements:
  – Assessment and documentation of symptom complaints
  – Physical findings
  – Laboratory values (i.e., CBC)
    • Not one specific biological test due to variety of hazards and target organs
Medical Surveillance General Principles

• When to conduct surveillance:
  – Initial baseline prior to assignment
  – Periodic assessment (1-3 years)
  – After an acute exposure
  – At exit or transfer

• Why: identify deviations from expectations
  – Second line of defense
  – Identify and correct any failures in primary prevention
  – Limit and prevent any adverse health outcomes
Medical Surveillance General Principles

• Who to include is based upon risk assessment

• All employees who prepare, administer, dispose of, or otherwise handle hazardous drugs or excreta from patients who have received hazardous drugs

• Could include but not limited to; physicians, nurses, pharmacists, pharmacy technicians, housekeepers and employees involved in receiving, transport, or storage and/or disposal
Medical Surveillance General Principles

• Recommended elements to capture:
  – Occupational history
    • Past exposures
    • Hours spent handling hazardous drugs
  – Reproductive and general health questionnaires (health history)
  – Laboratory studies/biological monitoring

• Additional elements:
  – Opportunity for confidential discussion of health concerns (Employee and OH)
  – Post – exposure management
Elements of Medical Surveillance

• Ensure alignment with your HR policies
• Determine if there are any state laws that would apply
• Can be done internally through OH or through a contracted service
• HIPAA applies, confidentiality is crucial
• Paper versus electronic
Elements of Medical Surveillance

- Medical history
- Reproductive history
- Work history to assess exposures to HDs
- Estimated number of HD handled per week
- Records of HD handled with quantities
- Estimated hours spent handling HD per week/month
- Exposure history
Medical Surveillance – Paper Version

Medical Survey for Persons who are at Risk of Occupational Exposure to Hazardous Drugs

CONFIDENTIAL

BJC HealthCare

Your name: ____________________________

Department: ____________________________

Today’s date: ____________________________

Medical History

1. In the past year, have you had any changes in your general health? Y N

If yes, please describe: ____________________________

2. In the past year, have you had any of the symptoms listed below?

<table>
<thead>
<tr>
<th>Symptom</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin rash</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wheezing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other specific: ____________________________

Have you noticed any of the above symptoms occur in relation to your work week? Y N

(e.g., either during the work day or immediately after)

If yes, please describe: ____________________________

3. In the past year, have you had a significant, unintentional weight loss? Y N

If yes, how many pounds? ____________________________

4. In the past year, or since you last completed this questionnaire, have you had any of the following reproductive events listed below?

a. Have you or your partner had a problem conceiving a child? Y N

b. Have you or your partner consulted a physician for a fertility or other reproductive problem? Y N

c. If yes, please specify who consulted the physician: ____________________________

   a. Self
   b. Partner
   c. Self & Partner

d. In the past year, have you or your partner taken a birth control pill? Y N

   a. Yes
   b. No

   If yes, please specify the type of pill: ____________________________

   a. Ovulation inhibitor
   b. Progesterone
   c. Contraceptive implant
   d. CG or other injectable
   e. Natural family planning
   f. Other

   If the pill was an oral contraceptive, please specify the type or brand: ____________________________

5. In the past year, have you developed any mental health irregularities? Y N

   If yes, please specify the type of mental health irregularity: ____________________________

   a. Depression
   b. Anxiety
   c. Bipolar disorder
   d. Schizophrenia
   e. Other mental health disorder

6. What is the occupation of your spouse or partner? ____________________________

Medical History – Paper Version
# Medical Surveillance – Electronic Method

**Medical Survey For Persons Who Are At Risk Of Occupational Exposure To Hazardous Drugs**

**Your Name:**

**Your Employee Number:**

**Email Address:**

**UserID:**

## Medical History

1. In the past year have you had any changes in your general health?
   - [ ] No  [ ] Yes
   
   If yes, please describe:

2. In the past year have you had any of the symptoms listed below?

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>No / Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breathing difficulties</td>
<td>No       Yes</td>
</tr>
<tr>
<td>Bruising</td>
<td>No       Yes</td>
</tr>
<tr>
<td>Dizziness</td>
<td>No       Yes</td>
</tr>
<tr>
<td>Facial flushing</td>
<td>No       Yes</td>
</tr>
<tr>
<td>Fever</td>
<td>No       Yes</td>
</tr>
<tr>
<td>Gastrointestinal complaints</td>
<td>No       Yes</td>
</tr>
<tr>
<td>Hair loss</td>
<td>No       Yes</td>
</tr>
<tr>
<td>Headache</td>
<td>No       Yes</td>
</tr>
<tr>
<td>Nausea</td>
<td>No       Yes</td>
</tr>
<tr>
<td>Nosebleed</td>
<td>No       Yes</td>
</tr>
<tr>
<td>Skin rash</td>
<td>No       Yes</td>
</tr>
<tr>
<td>Sore throat</td>
<td>No       Yes</td>
</tr>
<tr>
<td>Vomiting</td>
<td>No       Yes</td>
</tr>
<tr>
<td>Wheezing</td>
<td>No       Yes</td>
</tr>
</tbody>
</table>

Other Symptoms (specify):

Have you noticed that any of the above symptoms occur in relation to your work week? (e.g. either during the work day or immediately after)  [ ] No [ ] Yes, If yes describe below:

---

**BJC HealthCare**  
*Confidential*

**Occupational Health Services**

---

**BJC The world’s best medicine. Made better.**
3. In the past year have you had a significant, unintentional weight loss?
   - No
   - Yes, how many pounds?:

4. In the past year, or since you last completed this questionnaire, have you had any of the following reproductive events listed below?
   - Have you or your partner had a problem conceiving a child?  
     - No
     - Yes
   - Have you or your partner consulted a physician for a fertility or other reproductive problem?
     - No
     - Yes, Please specify who consulted the physician: - choose -

If yes, please state the diagnosis that was made:

- In the past year have you or your partner had a miscarriage, still birth or infant born with a birth defect?
  - No
  - Yes, Please specify the type of outcome: - choose -

If the outcome was a birth defect, please specify the type or describe:

- In the past year, have you developed any menstrual irregularities?
  - No
  - Yes
  - Not Applicable

If yes, please specify the type of menstrual irregularity:

- How many episodes of this irregularity did you have (in past year)?

5. What is the occupation of your spouse or partner?
## Medical Surveillance – Electronic Method

### Work History

1. Approximately how many hours a week do you spend mixing, transporting or administering hazardous drugs; or handling patient waste or linens contaminated with hazardous drugs? □ choose □

   - Identify your activities (check all that apply)  □ Mixing  □ Transporting  □ Administering Handling: □ Contaminated Patient Waste  □ Contaminated Linens

   Describe any other activities below:

2. Has this schedule changed over the past year?  □ No  □ Yes, Describe how it changed?

3. In the past year have you been around a hazardous drug spill?  □ No  □ Yes
   
   If yes, what was the drug name?

   Give approximate date or dates (if this occurred more than once)

   Approximately how large was the spill? □ choose □

   Did you clean it up?  □ No  □ Yes

   What protective clothing were you wearing when the spill occurred, and during clean up?

4. In the past year have you had an unprotected exposure to hazardous drugs through accidental ingestion, inhalation or skin contact?  □ No  □ Yes, how many times this past year? □

   Describe the exposure(s):

   What was the drug name?

   Was the potential exposure reported to Occupational Health?  □ No  □ Yes
Medical Surveillance – Electronic Method

5. Please choose most appropriate answer as it applies to your hazardous drug handling practice:

<table>
<thead>
<tr>
<th>When handling hazardous drugs</th>
<th>Always</th>
<th>Often</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>I wear disposable gloves.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I wear double gloves.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I change my gloves according to the guidelines on my unit.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I wear disposable gowns.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I wear goggles.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I wear a face shield.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I wear a protective/surgical mask.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I wear an N95 respirator.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I wear disposable booties/shoe covers.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I wear disposable hair covers.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>If I mix drugs, I use a biological safety cabinet.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>I use closed system transfer devices.</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

Do you want to talk to Occupational Health regarding hazards of drugs? ○ No ○ Yes

☐ By checking this box, clicking the submit button (my 'electronic signature'), I attest that the information provided on the form above is true and correct to the best of my knowledge. I further understand and agree that my electronic signature has the same force and effect as if I had affixed my hand-written signature to this record.
Medical Surveillance – Electronic Versus Paper

**Electronic**
- **Pros:**
  - Data entered automatically into confidential electronic database
  - Ability to run trend reports electronically
  - Ability to track compliance
- **Cons:**
  - Requires electricity and computer

**Paper**
- **Pros:**
  - No electricity or computer required
- **Cons:**
  - Track piece of paper
  - Manual data entry into an electronic database for trending and reporting
  - Easily lost
  - Difficult to track who has completed
Our Process

• Surveillance questionnaire completion:
  – Electronic with auto insertion into OH database
  – Revise questionnaire for flow and ease of completion
  – Tie to education completion via SABA
  – Annual completion (easier to track)

• Physician referrals:
  – Adverse outcomes identified
  – Employee request
  – Significant unprotected exposures
Data Analysis and Reporting

• Remember the WHY

• Reporting:
  – Provide epidemiologic approach
  – Exposure tracking

• Surveillance track for changes over time:
  – Individual for health changes
  – Worker population as a whole
  – Monitor future health as it relates to a potential exposure to hazardous drugs

• Provides:
  – Early detection of problems
  – Identification of failure of prevention measures
Laboratory Testing Questions

• No recommended safe exposure levels for hazardous drugs

• CBC, liver function, reticulocyte count, urine – abnormalities attributed to HD exposure only?, impractical, useful?

• Biological testing – measures specific drug or metabolite
  – Feasibility questionable – multiple hazardous drugs
  – Difficult to interpret results
  – Not all labs can conduct testing
  – Used in research, not meant for exposures in individuals
OSHA Statements Regarding Lab Tests

- Determine any pre-existing blood condition (that may place the worker at increased risk when handling HDs)
- Complete blood count with differential
- Additional lab testing (liver function tests, blood urea nitrogen, creatinine, and a urine dipstick for blood) may sometimes be appropriate
- Biological monitoring, i.e., the measure of a specific agent or its metabolite in a body fluid (such as a urine 5-FU level), is also not recommended for a screening protocol on a routine basis due to the large number of agents an employee handles on a given work shift.
- At the discretion of a physician, as a function of the medical history obtained, or as part of a formal surveillance program with well-defined goals.
NIOSH Statement Regarding Lab Tests

• “Because healthcare workers are typically exposed to numerous hazardous drugs [NIOSH 2004; 2012], no single biological monitor is suitable for all of these drugs. Organizations should use the information obtained through medical surveillance to help affected workers and to identify and correct system failures that may have resulted in harmful exposures.”
Development of Follow-up Plan

• When to implement follow-up:
  – Surveillance suggesting health changes
  – Post acute exposure (substantial skin contact or inhalation exposure, cleaning a large spill)

• Physician evaluation:
  – Post-exposure
  – Employee request
Post Exposure OH Role

- Exposure definition
- Instructions on what to do for personnel contamination
- When to seek immediate medical attention, i.e., inhalation, acute symptoms
- How to report an exposure
- Assign roles for OH and EH&S
- Consult SDS for drug-specific information/medical treatment
- How to manage contaminated employee clothing
Follow-up Process

• Post-exposure examination should be tailored to the type of exposure
  – Assessment of the extent of exposure
  – Physical assessment and testing should focus on the involved area as well as other organ systems commonly affected
  – Maintain confidentiality

• Evaluate current protective measures
  – Engineering Controls – evaluate performance, are they working? Do they align with current standards?
  – Administrative controls – were policies followed? Any gaps?
  – PPE: was the appropriate PPE available and was it used properly?
Follow-up Process

• Develop an action plan to prevent further exposures
• Re-evaluate to ensure action plan is working
• Maintain an open door between OH and the workers
  – Notifications
  – Changes in health
  – Detection of an adverse health effect
• Ensure that any exposed worker receives confidential notification of any adverse health effect. Offer alternative duty or temporary reassignment
• Utilize your ongoing medical surveillance to determine plan effectiveness
Recordkeeping — OSHA

- Maintain exposure data for at least 30 years
- Background data related to environmental, or workplace, monitoring or measuring must only be retained for 1 year, so long as you preserve certain interpretive documents relevant to the interpretation of the data for 30 years
- "Analyses using exposure or medical records." Each analysis using exposure or medical records shall be preserved and maintained for at least thirty (30) years
Process in Hazardous Drug Policy

- Statement that you will provide medical surveillance
- Who will be included in the medical surveillance program.
- Who will manage/coordinate the medical surveillance program.
- Elements of the medical surveillance program
- When employees are referred to a physician
Acknowledgement of Risk

• **Definition:** A written confirmation that personnel understand the risks of handling hazardous drugs

• Personnel of reproductive capability must confirm in writing that they understand the risk of handling HDs

• USP 797 since 2008 and is a requirement of USP 800

• Joint Commission requirement that the organization advises all compounding staff of the risks to their reproductive systems when handling HDs and confirms that staff understand these risks
Acknowledgement of Risk

• Training must be completed first:
  – Risks working with or near hazardous drugs
  – Policies and procedures
  – Opportunity for questions

• Attach to education

• Statements should be explicit, thorough and clear
  – “Understand that working with or near hazardous drugs in health care setting may cause skin rashes, infertility, miscarriage, birth defects, and possibly cancer”
  – Understand policies and procedures (fact based and reviewed/revised)
  – Provided training
  – Agree to comply with policies/procedures
  – Agree to ask questions if needed
  – Failure to comply with policies places at risk
Reproductive Risk

- Declaration of pregnancy or intent to conceive
- Workers who are actively trying to conceive, are pregnant, or are breast-feeding can request alternative duty or protective reassignment
- Alternative duty is voluntary and personnel are responsible for informing employers of their desire to avoid handling HD
- Can utilize private physicians to validate request for alternate duty
- Human Resources and the employee’s manager should manage these requests
Occupational Health and Pharmacy: An Important Partnership

• Important parallel and intersection between pharmacy and occupational health:
  – Shared responsibility in the ongoing management of critical environments where sterile compounding is conducted;
    • Know where sterile compounding is occurring (e.g. outpatient clinics, doctor’s offices)
  – Ensure potential sources of environmental contamination are identified during routine environmental monitoring and remediated as needed.
  – Provide insight and assistance to the pharmacy team to maintain a state of control in critical compounding environments ensuring ongoing safety and quality!
Conclusion

• Compounding and hazardous drug handling is associated with many risks for the employee and patients
• Our organization has committed to standardizing as much of the approaches as is feasible including:
  – PPE (types, when and how)
  – Workflows
  – Medical surveillance and acknowledgement of risk
  – Facility design (primary engineering control)
  – Secondary engineering controls (CSTDs)
  – Training
  – Assessment of risk (standardized approach to specific medications based on risk of activity being performed)
  – Policy and procedures, including how hazardous medications are handled
• Changes are coming to a facility near you in December!
References and Resources

- Centers for Disease Control, [https://www.cdc.gov/niosh/topics/hazdrug/default.html](https://www.cdc.gov/niosh/topics/hazdrug/default.html)
- National Institutes of Health: [https://www.cdc.gov/niosh/docs/2016-161/default.html](https://www.cdc.gov/niosh/docs/2016-161/default.html)
- United States Pharmacopial Convention, USP Chapter 800: [https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare](https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare)
- Occupational Safety and Health Administration: Controlling Occupational Exposure to Hazardous Drugs [https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html](https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html)
- Oncology Nursing Society: Toolkit for Safe Handling of Hazardous Drugs for Nurses in Oncology [https://www.ons.org/sites/default/files/2018-06/ONS_Safe_Handling_Toolkit_0.pdf](https://www.ons.org/sites/default/files/2018-06/ONS_Safe_Handling_Toolkit_0.pdf)
- ASHP Guidelines on hazardous drug management: [https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/handling-hazardous-drugs.ashx](https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/handling-hazardous-drugs.ashx)
- Kienle, Patricia C., The Chapter <800> Answer Book, American Society of Health-System Pharmacists, Inc. 2017
What Questions Do You Have?

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